IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

UNITED STATES OF AMERICA	)	
	)	
	)	No. 2:19-cr-00010
v.	)	
	)	Judge Campbell
	)	
GILBERT GHEARING	)	

UNITED STATES' DISCLOSURE OF ANTICIPATED EXPERT WITNESSES AND ADDITIONAL EVIDENCE

The United States, through undersigned counsel, hereby files this updated and revised Disclosure of Anticipated Expert Witnesses and Additional Evidence, pursuant to the Court's Scheduling Order entered in this case [D.E. 183], and Federal Rules of Evidence 702, 703, and 705, and Federal Rule of Criminal Procedure 16(a)(1)(G).

This Disclosure is intended to supplement and update the disclosures and discovery that the United States has previously provided to Defendant.

The United States does not contend or concede that every portion of the testimony described below necessarily qualifies as expert testimony under the Federal Rules of Evidence or implicates the disclosure requirements of Federal Rule of Criminal Procedure 16. Nonetheless, the United States provides this updated and revised disclosure in the event the Court concludes that the testimony described herein constitutes expert opinion testimony. Further, the United States may elect not to elicit all the testimony outlined in this disclosure.

NOTICE OF POTENTIAL EXPERT WITNESSES

Medical Expert – David A. Edwards, MD PhD

I. Statement of Opinions, Bases and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C), and the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii). This disclosure supplements the United States' previous disclosures of Dr. David Edwards' testimony, including the version provided on July 20, 2022 to the Defendant.

The Government intends to call Dr. David Edwards, to testify regarding the field of pain medicine and pain management, the nature of pain and types of pain, treatment of pain, and the medically appropriate and inappropriate uses of controlled substances in treatment. Dr. Edwards has not written a report or reviewed patient files in this case.

Bases for Testimony:

Dr. Edwards' opinions are based upon his education, personal medical training, research, interactions with patients, interactions with other physicians, and experience in the fields of pain medicine and anesthesiology. Dr. Edwards will help the jury understand how pain impacts the body, how the diagnostic treatment process works, treatments for pain, and the nature and appropriate uses of controlled substances in the treatment of pain. Dr. Edwards will also help the jury understand the limitations and risks of controlled substances.

He will rely on reference to the Tennessee Chronic Pain Guidelines, Tennessee Pain Clinic Guidelines, Tennessee Board of Medicine standards of conduct, applicable Tennessee Code Annotated sections on pain treatment and pain management clinics, medical treatment, and opioid prescribing, Controlled Substances Act and regulations governing DEA registrations, American Medical Association Code of Medical Ethics, CDC and FDA guidelines, the Code of Federal

Regulation, opioid treatment tools, as well as respected, peer-reviewed, medical and scientific literature.

Opinions and Summary of Anticipated Testimony: The government anticipates Dr. Edwards' testimony may cover the following topics.

- Dr. Edwards will discuss his background as described in greater detail in his CV.
- He will explain in detail:
    - The nature of different types of pain;
    - pain medicine treatment;
    - various forms of pain treatment;
    - diagnostic techniques;
    - identification and explanation of controlled substances, and schedules;
    - how opioids and other controlled substances work in the body;
    - the addictive risks of controlled substances including oxycodone, hydrocodone, alprazolam, and others;
    - opioid pain management treatment, when it should be used, the risks, and side effects;
    - the doctor / patient relationship;
    - physical examinations and the need to request and verify the previous medical history of a patient when dealing with controlled substances;
    - education and informed consent;
    - risks and dangers involved with prescribing certain combinations of controlled substances;
    - importance of the controlled substance monitoring;

- role and importance of documentation;
- risks and signs of use disorders and associated courses of action;
- laws and guidelines governing prescribing and pain management;
- what a medical license and DEA registration authorizes a provider to do with regard to controlled substance prescribing.

- Dr. Edwards will explain that the Tennessee Chronic Pain Guidelines started in 2013 to educate all levels of medical providers and applies to all medical providers whether they are in a rural or urban setting. He will explain the recommendations in the guidelines. He will state that the guidelines anticipate deviations from the rules for appropriate medical reasons, but that those deviations are expected to be documented. He will explain the importance of accurate and individualized documentation.
- Dr. Edwards will explain that other rules, regulations, and guidance inform medical providers about the accepted professional standards for prescribing controlled substances nationally, and in Tennessee. He will explain where the standards come from and how they are taught. He will explain that providers are governed by national board standards for the physician's board certification, license standards for their state, and legal regulations like state laws and DEA registration rules. He will explain that physicians are required to follow the law.
- Dr. Edwards will explain there is a difference between acute pain and chronic pain, and that chronic pain can be broken down into various categories, including nerve pain, central pain, and inflammatory pain.

- Dr. Edwards will describe the different goals in treating pain depending on the individual patient, including to feel better, perhaps obtain functional improvement, or to not worsen.
- The government anticipates that Dr. Edwards will explain what the usual course of treatment looks like for a hypothetical chronic pain patient, including the diagnostic process or work up, assessment, medical history, social status, physical examination, reaching a differential diagnosis, and treatment plans. He will explain the doctor and patient set functional goals. That diagnostic tests, activities and therapies, psychological therapies, and interventional therapies, and medications can be part of the treatment plan. That treatment is targeted to the particular type of pain. Treatment is individualized to a particular patient's needs and periodic review of progress and monitoring is part of treatment. He will explain that controlled substances are rarely the first treatment and that when it is initiated it is part of multimodal pain control plan of care and is started at lowest effective dose. Informed consent from patients is obtained. Patients are educated on the risks and benefits, including risks to look for like slow breathing and sleepiness, and are monitored and assessed.
- Dr. Edwards will explain that as part of a patient work up a doctor assesses a patient's pain by inquiring into the duration, forms of alleviation, what exacerbates it, testing anatomical clues like radiation of the pain, and listening to the patient's qualification of the pain.
- Dr. Edwards will explain that for the average chronic pain patient he does not start out prescribing controlled substances as the first form of treatment. That opioids should be considered the last resort for chronic, nonmalignant pain. That the fact a patient was

prescribed a controlled substance by a prior provider is not itself a reason to continue the medication. That opioids should be used only after other treatments and medications have failed. That medical history, examinations, tests, and plan of care should be well documented before controlled substances are started.

- He will explain the importance of using agreements with patients for pain treatment and engaging in an initial trial period of medications when other treatments have been tried and failed. That the patient then starts on lowest dose for shortest duration and is monitored for benefits and improvement in function.
- He will explain that monitoring and following up with patients on medication based treatment is important and part of the usual course of professional practice and that he looks for side effects that suggest the trial period is failing, like sleepiness, dizziness, inability to function, constipation, and nausea.
- He will explain the treating physician has a responsibility to keep the patient safe and that includes monitoring patients for aberrant behaviors when they are taking controlled substances. To trust but verify, with the goal of protecting patients from themselves. This includes protecting them from misuse and loss of control, and use disorders, including through conducting laboratory confirmation testing, validating medical questions and identifying risk factors through risk assessment tools, conducting checks of the controlled substance monitoring database, checking for illegal drug use, conducting pill counts, and other follow-up. Aberrancies may also include running out of pills too early, taking too much of a medication, going to other doctors for prescriptions, and otherwise violating the pain agreement.

- Where substance use disorder is suspected, the provider should make appropriate referrals and coordinate care.
- He will explain that long term opioid use can make pain worse through a condition called opioid induced hyperalgesia, because it impacts tolerance and is less effective over time.
- Tolerance and dependence are different and dependence can lead to withdrawal symptoms from controlled substances.
- Dr. Edwards will explain there are serious dangers in prescribing certain controlled substances in combination that lead to increase risk of overdose and death. He will also explain that benzodiazepines mixed with alcohol is a serious patient safety risk that is known to prescribers. He may explain what an overdose is and that overdosing is the top cause of accidental death in the United States.
- He will explain what Narcan/naloxone is, and that he prescribes it as part of his usual practice. He will explain what buprenorphine is and what it is used for and how it impacts treatment in a patient being treated for pain.
- Dr. Edwards may answer hypothetical questions and opine whether courses of treatment or medications prescribed and described in hypotheticals constituted an appropriate practice of medicine within the usual course of professional practice, or was for legitimate medical purposes or medically necessary. Dr. Edwards will explain that the Tennessee Chronic Pain Guidelines are a recognized standard that applies to all medical providers in Tennessee. He will explain how they are made available to medical providers and the continuing education requirements regarding controlled substance prescribing.

- Dr. Edwards will explain that in the treatment of pain the primary responsibility of the prescriber is to keep the patient safe, to provide treatment, to do no harm. That a provider also has a responsibility to all patients and society to ensure access to medical care.

II. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

Dr. Edwards will provide expert testimony in the field of pain medicine and pain management based on his educational background, training, and experience, as detailed in his CV, which has been separately provided to the Defendant and is incorporated by reference. He is an Associate Professor of Anesthesiology and Neurological Surgery and Chief of the Division of Pain Medicine at Vanderbilt University Medical Center. He oversees and personally cares for patients in several specialty clinics that treat patients for cancer-related pain, chronic pain, operative pain, and high-risk patients admitted to the hospital with pain or substance use disorder. His research is focused on the transitional care of patients in the perioperative period, and the functional recovery of postoperative patients.

Dr. Edwards is board certified in Pain Medicine and Anesthesiology. Dr. Edwards specializes in adult anesthesiology, and adult and pediatric pain medicine. He is an expert in acute and chronic pain and in the use of pain relief and analgesics. He has particular knowledge of opioids and cannabinoids and how they affect the nervous system. He has lectured extensively on these topics, as demonstrated by his CV. Dr. Edwards' CV sets out his qualifications in greater detail.

Publications: Dr. Edwards has authored several publications in the previous 10 years. A list of these publications is available in Dr. Edwards' CV.

III. List of Cases

Below please find "a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition." Fed. R. Crim. P. 16(a)(1)(G)(iii).

(1) July 16, 2020, deposition, under seal, information to be separately provided to defense counsel under the protective order in this case;
(2) October 10, 2022, deposition, testimony as a witness as treating physician of patient in case in Tennessee State Court, *Edwards v. Whitaker.*

Defense counsel will also be provided with a current C.V. Dr. Edwards has been informed that if he learns of testimony that should be disclosed under this rule to notify the government.

Dr. Edwards has reviewed and approved this disclosure as demonstrated by his attestation below.

I have reviewed and I approve this disclosure.

Date: 2/6/2023

David A. Edwards, MD PhD

NOTICE OF POTENTIAL EXPERT WITNESSES

Medical Expert – Carl Christensen, M.D., PhD, cMRO

I. Statement of Opinions, Bases and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C), and the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii).

The Government intends to call Dr. Carl Christensen, to testify regarding pain medication management and addiction and a review of records related to Defendant's patients, including the seven patients named in the Superseding Indictment.

Bases for Testimony:

Dr. Christensen's opinions are based upon his education, personal medical training, research, interactions with patients, interactions with other physicians, and experience in the fields of addiction and pain medication management. Dr. Christensen will provide expert opinion testimony based on that educational background, training, and experience, as detailed in his CV, which has been provided to the Defendant and is incorporated by reference. Dr. Christensen is a specialist in the field of addictionology and pain medication management, and like the Defendant, is an OB/GYN.

The United States anticipates that Dr. Christensen will testify about what constitutes a legitimate medical purpose within the scope of professional practice in the field of medical practice. We anticipate that Dr. Christensen will also testify about the purpose and appropriate use of a DEA number, and corresponding responsibility when prescribing Schedule II through V controlled substances and non-controlled substances. He may testify about the importance of reaching the correct diagnosis and offering the correct treatment for each individual patient. He

will also discuss the signs and dangers of addiction/use disorders and dangers of combining opioids with other controlled and non-controlled substances, like alcohol. He will testify about his medical expert review of Defendant's patient files and his conclusions that Defendant prescribed controlled substances outside the usual course of professional practice not for legitimate medical purposes.

Opinions and Summary of Anticipated Testimony: The government anticipates Dr. Christensen's testimony may also cover the following topics.

Dr. Christensen conducted a file review for the patients listed in the indictment. He also reviewed other patient medical records, PDMP/CSMD records for the Defendant and patients, and the undercover visits. Dr. Christensen will provide testimony and expert opinion in connection with that patient file review. Dr. Christensen may opine on hypotheticals related to evidence in this case. The United States incorporates Dr. Christensen's written expert reports into this disclosure, which have been previously produced to Defendant.

The United States expects Dr. Christensen to testify specifically about Defendant's prescribing practices, and how Defendant's conduct relates to the usual course of professional practice. Furthermore, the Government anticipates Dr. Christensen to testify that the conduct and prescriptions at issue were outside the usual course of professional practice, not for legitimate medical purposes. His methods, sources, and findings are identified in his reports, which have been previously disclosed to counsel for defendant in March and April 2020 and July 2021, and revised in July 2022. Dr. Christensen reviewed both an original set of patient records, and records obtained in October 2021 that contained post-indictment alterations by Defendant. The United States anticipates that Dr. Christensen will provide testimony consistent with the findings in these reports.

In addition to providing expert opinion testimony related to the patient file review, Dr. Christensen may present testimony on the following general topics based on his specialized education, training, and experience, and in particular, in addiction:

- What constitutes a legitimate medical purpose within the scope of professional practice in pain medication management and addiction medicine/use disorders.
- The legitimate medical purposes of the drugs at issue in this case, such as oxycodone, muscle relaxers, and benzodiazepines, including testimony about drug interactions, contraindications, potentiating effect, and the prescribing of therapeutic versus non-therapeutic amounts;
- He may testify about the ethical considerations of a physician, including doing what is best for a patient and not doing harm.
- Dr. Christensen will also testify about the risks associated with prescribing opioid and/or benzodiazepines, and why it is necessary to prescribe controlled substances only for a legitimate medical purpose in the course of professional practice in order to mitigate those risks. For example, he may testify about:
    - Various studies documenting the dangers of opioid usage, including the "Boehnert" study, the "Dunn" study, the "Gomes" study, and The Tennessee Chronic Pain Guidelines and the CDC Guidelines.
    - He will testify about the dangers (including death and addiction) as well as the ineffectiveness of prescribing opioids, benzodiazepines, and muscle relaxers. Dr. Christensen will refer to the 2016 Food and Drug Administration black box warning regarding the serious dangers of concurrently prescribing opioids and benzodiazepines.

- The risk of physical dependence and withdrawals.
- The risk of addiction, particularly opioid addiction, the signs of addiction, the impact of addiction on the patient and the patient's friends and family, treatment of addiction, and the dangers of overdose and death from drug misuse and abuse.
- The potential for misuse of controlled substances, and their addictive properties. He will further testify about a physician's duty to watch for signs of abuse, addiction, and diversion in the usual course of professional practice, and the warning signs and diagnostic tools prescribers use in the usual course of professional practice to determine whether a patient is suffering from addiction.
- He may testify about the nature of addiction and use disorders and how addiction operates on the brain and the symptoms of addiction. He will explain that addiction can be fatal. That a doctor who continues to prescribe to someone with a use disorder prolongs the illness, makes it worse, makes it harder to treat, and increases risks to the patient.
- Prescribers should use addiction questions to assess risks for use disorders. If the correct diagnosis of a patient is addiction/use disorder, it is not a legitimate medical purpose to continue to prescribe substances they are addicted to. It is not a legitimate medical purpose to prescribe controlled substances to a patient just because they beg for it or are trying to avoid withdrawal symptoms.
- Other risks and side effects of opioid use.
- Long acting versus short acting opioids.
- The number of overdoses in carefully managed family practice and pain management practices is normally extremely low. However, when the physicians

in charge of treatment abdicate their responsibilities to honestly convey the risks associated with any given treatment, overdoses can occur.

- The United States expects that Dr. Christensen will provide expert opinions as to Defendant's prescribing and dispensing practices, based on his review of patient files and records, and the Tennessee Controlled Substance Monitoring Database (CSMD) including:
    - The controlled substances prescribed by the Defendant to the patients listed in the indictment were not prescribed in the usual course of professional practice for a legitimate medical purpose.
    - Dr. Christensen will testify consistent with the disclosed reports regarding his analysis of individual patient files. In addition, he will incorporate the patient's overall history, as documented by the defendants' medical files and CSMD, in reaching his conclusion that the charged prescriptions were not written for a legitimate medical purpose in the course of professional practice.
    - As part of this discussion of the Defendant's prescribing practices, he will testify about applicable state and federal guidelines related to controlled substances use and distribution, as well as guidance relating to appropriate pain medication management practice. In addition, he will testify about specific procedures that comprise the scope of professional practice in medical practice and with respect to opioid and benzodiazepine prescriptions and will explain how those procedures are used to mitigate and monitor risk factors. For example, he will testify about urine drug screens (including their purpose and limitations), maintaining patient files, the importance of monitoring PDMP/CSMD databases, and the importance of physical examinations and other diagnostic testing.

- The CSMD data for Defendant's charged patients.
- That Defendant's patients suffered substance use disorders and the Defendant inappropriately prescribed in light of demonstrated use disorders, abuse, diversion, and overdoses.
- He may testify about the alterations in Defendant's patient records made by the Defendant in December 2019 and January 2020 related to the patients reviewed by Dr. Christensen. He may discuss the importance of documentation practices and his own practices.

In reaching his conclusions, Dr. Christensen has relied on his knowledge, training, skill, and experience as well as other sources as listed in his reports and prior disclosures. Dr. Christensen reserves the right to supplement his respective opinions as necessary to address the issues raised in this case, including rebuttal of Defendant's expert witnesses. He may review additional material prior to and during trial to further ensure the opinions remain accurate and complete.

II. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

Dr. Christensen is a medical doctor, with special focus in the clinical areas of pain medication management and addiction. He has over 40 years' experience as a medical doctor. Dr. Christensen is certified in addiction medicine and is an OB/GYN. He serves as a clinical associate professor at Wayne State University of Medicine and has published many medical articles on addiction and pain, and regularly speaks and trains other doctors. He is recognized as a Distinguished Fellow by the American Society of Addiction Medicine. He has previously been

qualified as an expert witness in Federal Courts on pain medication management and addictionology. Dr. Christensen's CV sets out his qualifications in greater detail.

Publications: Dr. Christen has authored several publications in the previous 10 years. A list of these publications is available in Dr. Christensen's CV as well as an updated disclosure provided to Defendant.

III. List of Cases

Below please find "a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition." Fed. R. Crim. P. 16(a)(1)(G)(iii).

(1) Pompy, Lesly MD: December 6-8, 2022; Detroit MI (Federal Trial)

(2) Robertson, Jonathan DO: June 22, 2022; Marquette, MI (Criminal Trial)

(3) Small, Matthew MD: Jan 27, 2022 and Feb 25, 2022 (preliminary hearing); South Haven, MI (Criminal Trial), dismissed 12.21.22.

(4) Smith, Bowdoin MD: Daubert Hearing, Nashville TN: Sept 29, 2021

(5) Kue, Eleanore MD: Admin Law Hearing, Lansing, MI: Feb 5th, 2021

(6) Lloyd-Turney MD: January 31, 2020; Federal Trial, Huntsville Alabama

(7) Brown, Remona NP: Preliminary Hearing, November 22, 2019; Lansing MI

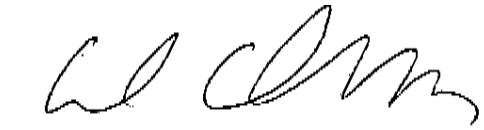
(8) Robertson, Jonathan DO: Preliminary Hearing; October 3, 2018; Marquette MI

Dr. Christensen has been informed that if he learns of testimony that should be disclosed under this rule to notify the government.

Dr. Christensen has reviewed and approved this disclosure as demonstrated by his attestation below.

I have reviewed and I approve this disclosure.

Date: February 5, 2023



Carl Christensen, MD, PhD, cMRO

Controlled Substance Monitoring Database ("CSMD") Witness – Peter Phillips, D.Ph.

I. Statement of Opinions, Bases, and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C), and the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii).

The Government intends to call Dr. Peter Phillips to explain how the CSMD works in Tennessee. He will describe why and when the CSMD was established, what data it collects and from whom, and who is required to use it. He will also discuss the rules and regulations that govern use of the CSMD and the consequences of not using it as required. He will describe how reports are generated and how the Board of Pharmacy monitors the CSMD.

Bases for Testimony:

Dr. Phillips' opinions are based largely upon his more than twenty-five years of experience as a licensed pharmacist and his role as Director of the CSMD Program. Dr. Phillips will help the jury understand what the CSMD is, how data is entered into the CSMD, how it generates reports, and how it is used by prescribers and dispensers of controlled substances.

Opinions and Summary of Anticipated Testimony: The government anticipates that Dr. Phillips' testimony may cover the following topics, including his background as included in his curriculum vitae ("CV"):

Information about the CSMD Program generally, including:

- CSMD is the database utilized by the Tennessee Department of Health to monitor the dispensing of controlled substances in Tennessee.

- Information contained in the CSMD is collected by software utilized by prescriber dispensaries or pharmacies.
- Some of the CSMD's uses are to curb doctor shopping and to monitor dangerous combinations of controlled substances.
- The CSMD can be used to generate reports in several different forms. Examples are a report of the controlled substances dispensed to an individual by all Tennessee pharmacies and a report of all controlled substances prescribed by a specific doctor.
- Dr. Phillips will describe the information contained within a CSMD report generated for one of Defendant Ghearing's patients.
- Dr. Phillips will describe the following CSMD rules and regulations governing pharmacists and prescribing practitioners:
    - Licensed prescribers of controlled substances are required to register with the CSMD.
    - Physicians who register with the CSMD are assigned a unique ID and password to access the CSMD. They can assign a delegate to check the CSMD.
    - Pharmacists' use of the CSMD is mandatory and they are subject to disciplinary action by the Board of Pharmacy if they do not input data correctly and in a timely manner.
    - Pharmacists are required by statute to enter information about controlled substances into the database by the end of the next business day after filling the prescription.

- Dr. Phillips will describe how the Department of Health conducts periodic audits to make sure the CSMD is being used correctly.
- He will explain that if a malfunction in a pharmacy's reporting software is detected, Dr. Phillips' team works with the dispenser to fix the issue.
- Dr. Phillips will explain what types of drugs are considered controlled substances, the fact that controlled substances are classified into schedules I-V and the meaning of each classification. He will explain why gabapentin became a controlled substance in Tennessee and when.
- Dr. Phillips will explain what he considers to be red flags in the context of filling prescriptions. Examples being high doses of a controlled substance, high quantities of a controlled substance, and early refills of controlled substances.
- Dr. Phillips will explain that it is not uncommon for a pharmacist to contact a physician if the pharmacist has concerns about a controlled substance prescription. He will testify that pharmacists have a duty to use their clinical judgment about the appropriateness of dispensing controlled substances and a pharmacist can refuse to fill a physician's prescription.
- Dr. Phillips will serve as a custodian of records for CSMD reports generated in relation to the investigation of Gilbert Ghearing, M.D. Thus, the government intends to admit through this witness the CSMD reports as identified in the provided Certificate of Authenticity of Domestic Records signed by Dr. Phillips.

II. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

Dr. Phillips is employed by the Tennessee Department of Health as the Director of the CSMD Program. He is also a licensed pharmacist in Missouri and Tennessee. Dr. Phillips' CV sets out his qualifications in greater detail, has been provided to defense counsel, and is incorporated into this notice.

Publications: Dr. Phillips has not authored any publications in the previous ten years.

III. List of Cases

The following is "a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition." Fed. R. Crim. P. 16(a)(1)(G)(iii).

1. *State v. Edward Ellis*, 2022-B-893, Davidson County General Sessions Court, July 20, 2022. Motion to Suppress Hearing. Dr. Phillips testified to admit CSMD records.

Please note that this list reflects Dr. Phillips' best efforts to account for his expert testimony over the previous 4 years. Dr. Phillips has been informed that if he learns of additional testimony that should be disclosed under this rule to notify the government.

Dr. Phillips has reviewed and approved this disclosure as demonstrated by his attestation below.

I have reviewed and I approve this disclosure.

Date: February 6, 2023

Peter J. Phillips, D.Ph.
Director of the Controlled Substance
Monitoring Database Program

Drug Enforcement Administration ("DEA") Diversion Witness – James Hischar

I. Statement of Opinions, Bases, and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C), and the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii).

The Government intends to call James Hischar to testify regarding the Controlled Substances Act and the Drug Enforcement Administration's ("DEA") registration requirement for prescribers and dispensers of controlled substances. He will testify as to which drugs are controlled substances under Federal Law and how controlled substances are classified by schedule. He will explain who is required to register with DEA and why. He will also discuss the rules and regulations that govern the prescribing and dispensing of controlled substances.

Bases for Testimony:

Agent Hischar's opinions are based largely upon his more than thirty-five years of law enforcement experience and more than a decade as a DEA agent. He will help the jury understand the DEA registration system and the nature of regulations and controlled substances. He will also rely on DEA rules and regulations.

Opinions and Summary of Anticipated Testimony: The government anticipates that Agent Hischar's testimony may cover the following topics, including his background as included in his curriculum vitae ("CV"):

Information about the Controlled Substances Act, DEA rules and regulations for the lawful distribution of controlled substances, and DEA Diversion investigations generally, including:

- What the Controlled Substances Act covers including the various schedules, the reasons each drug is scheduled, and the types of drugs included under each schedule.

- DEA registration and who may obtain one and how.
- The rules and regulations that govern a DEA registration.
- What information a valid prescription must contain and that to be authorized a prescription must be for a legitimate medical purpose and in the usual course of professional practice.
- Agent Hischar will describe the Modus Operandi evidence that law enforcement look for in controlled substances prescribing patterns. These include, for example, dangerous drug combinations such as opioids combined with benzodiazepines, and the numbers of prescriptions and amounts of pills.
- Agent Hischar will explain what methods physicians/medical personnel commonly employ to prevent patients from diverting prescription drugs.
- He will describe common practices of drug seeking patients and the methods patients use to circumvent drug screening and pill counts and the common practices that physicians employ to prevent patients from obtaining controlled substance prescriptions that are not medically necessary or outside of the usual course of professional practice.
- He will explain the ARCOs and Prescription Monitoring Database Program and what data these programs collect. He will explain who inputs the data and how it can be used by law enforcement in investigating prescribing and dispensing patterns.

II. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

Agent Hischar is a DEA Supervisory Diversion Investigator. Agent Hischar's CV sets out his qualifications in greater detail, has been provided to the defense, and is incorporated herein.

Publications: Agent Hischar has not authored any publications in the previous ten years.

III. List of Cases

The following is "a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition." Fed. R. Crim. P. 16(a)(1)(G)(iii).

1. *United States v. Fuhai Li*, 3:16-cr-194, testimony given on May 3, 2018. Agent Hischar was tendered as an expert in drug and diversion investigations. The District Judge declined to qualify Agent Hischar as an expert because the judge did not find that any opinions would be elicited from the witness and therefore, qualification as an expert was unnecessary.
2. *United States v. Raymond Kraynak*, 4:17-cr-403, testimony given on September 9, 2021. Agent Hischar testified about drug and diversion investigations.

Please note that this list reflects Agent Hischar's best efforts to account for his expert testimony over the previous 4 years. Agent Hischar has been informed that if he learns of additional testimony that should be disclosed under this rule to notify the government.

Agent Hischar has reviewed and approved this disclosure as demonstrated by his attestation below.

I have reviewed and I approve this disclosure.

Date: 02-07-2023

James J. Hischar

James J. Hischar
DEA Supervisory Diversion Investigator

The Government intends to introduce expert testimony regarding the functioning of the Medicare and Medicaid Programs, Medicare and Medicaid billing procedures and rules, Medicare and Medicaid auditing procedures and rules, rules relating to overpayment of claims, and the coverage requirements of services and items ordered by Defendant Ghearing resulting in claims submitted to Medicare and Medicaid by pharmacies.

As necessary, the Government will supplement this disclosure to identify any additional opinions or topics that the disclosed witnesses may cover or to address potential rebuttal testimony following Defendant's own expert disclosures.

NOTICE OF POTENTIAL EXPERT WITNESSES

Medicare Witnesses - Stephen Quindoza

I. Statement of Opinions, Bases, and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C), and the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii).

The Government intends to call Stephen Quindoza to explain how Medicare works (including both Parts B and D), Medicare's coverage for physician services and prescription drugs, that all claims submitted to Medicare for payment must be for reasonable and necessary items and services, and the representations that providers must make to enroll with Medicare. He will cover topics not otherwise covered by witness Johanna Sullivan, PharmD, Director of Clinical Operations, MEDIC. Mr. Quindoza will also describe the audit and review process by Medicare contractors, and what contractors look for in medical records. He will describe the rules and regulations regarding the maintenance of medical records by providers, including alteration or falsification of records.

Bases for Testimony:

Mr. Quindoza's opinions are based largely upon his more than forty years of experience working as a contractor for the Medicare Program, including his experience interpreting, applying, and ensuring compliance with applicable laws, rules, and regulations governing the payment of claims submitted to the Medicare Program. Mr. Quindoza will help the jury understand what Medicare is, what it pays for, and the mechanics of claim processing and reimbursement.

Opinions and Summary of Anticipated Testimony: The government anticipates that Mr. Quindoza's testimony may cover the following topics, including his background as included in his curriculum vitae ("CV"):

Information about the Medicare Program generally, including:

- Medicare is a federally funded health care program providing benefits to people 65 years of age or older or disabled. The United States Department of Health and Human Services ("HHS") is an executive branch agency. The Centers for Medicare & Medicaid Services ("CMS") is part of HHS and is responsible for the administration of the Medicare Program. Individuals who receive benefits under Medicare are referred to as Medicare "beneficiaries." Beneficiaries are eligible to receive a variety of services, including hospital and physician services ("Part B"). Part B covers outpatient physician services, such as office visits, when certain criteria are met. CPT codes are used for billing certain physician visits. "Part D" covers prescriptions for medications.
- Medicare and Medicaid are funded by United States taxpayers and affects interstate commerce;
- Medicare and Medicaid are "Federal health care program[s]" as defined in Title 42, United States Code, Section 1320a-7b(f) and "health care benefit program[s]" as defined in Title 18, United States Code, Section 24(b).
- Medicare is divided into four parts: coverage for in-patient care (Part A), coverage for medical items and services (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D).
- Physicians, other medical professionals, and other health care providers that provide items and services to Medicare beneficiaries are referred to as Medicare "providers" or

"suppliers." To participate in Medicare, providers and suppliers are required to submit an application in which they agree to abide by the laws, policies, procedures, rules, and regulations governing reimbursement. To receive Medicare funds, enrolled providers are required to abide by the laws, regulations, and policies, governing the program, including, but not limited to, several provisions of the Social Security Act, the regulations promulgated under the Social Security Act, and applicable policies, procedures, rules, and regulations issued by the Centers for Medicare & Medicaid Services ("CMS") and its authorized agents and contractors. Medicare manuals and service bulletins describing proper billing procedures, rules, and regulations are made available to providers.

- CMS assigns a unique identifier to each provider a number called a National Provider Identifier ("NPI"). The NPI is the standard unique health identifier for health care providers and suppliers and is assigned by the National Plan and Provider Enumeration System ("NPPES"). To enroll in Medicare, a provider must obtain an NPI and furnish it on their application prior to enrolling in Medicare or when submitting a change to their existing Medicare enrollment information. Applying for the NPI is a process separate from Medicare enrollment.
- If Medicare approves a provider's enrollment application, Medicare assigns the provider a Provider Transaction Access Number ("PTAN"). A provider who is assigned a Medicare PTAN and provides items or services to beneficiaries is able to order, among other things, durable medical equipment and laboratory testing. Claims for items and services are submitted for reimbursement to the Medicare contractor based on these orders.

- Medicare relies on providers to be truthful in attesting to their obligations in enrollment paperwork.
- Medicare is a trust-based system that relies on the honesty and integrity of its providers.
- Medicare providers, including physicians, must agree to follow the rules and regulations of the program.
- The Medicare program offers training and written guidance concerning these rules and regulations, many of which are publicly available.
- Defendant was enrolled in Medicare through the Form 855 and other documentation, including electronic funds transfer "EFT" forms, signed by Defendant and his assignees where he promised to comply with applicable rules and regulations and to not submit false claims.
- Defendant signed an EFT form that directed Medicare to deposit funds into a specific account.
- Medicare payments are often made directly to the supplier or provider who provided the item or service, rather than to the Medicare beneficiary. Payments occur when the provider submits a claim to Medicare or a plan administrator for payment, either directly or through a billing company.
- Other providers submit claims for items or services ordered by a physician like Defendant, including pharmacies.
- A Medicare claim is generally required to set forth, among other things, the beneficiary's name, the date the items or services were provided, the beneficiary's diagnosis, the name of the physician or provider who ordered the items or services, and the name of the physician or provider who provided the items or services. Providers

convey this information to Medicare by submitting claims electronically using billing codes and modifiers.

- After a claim is submitted and paid, Medicare will generate a remittance advice notice indicating what was submitted, what was processed, and what was paid by Medicare.
- Medicare regulations require providers to maintain complete and accurate patient medical records reflecting the medical assessment and diagnoses, as well as records documenting actual treatment of the patients to whom services were provided and for whom claims for payment were submitted by the provider. Generally, providers must disclose where such records are kept and maintain them for a period of 6 years. Medicare requires complete and accurate patient medical records so that Medicare can verify that the services were provided as described in the claim form. These records are required to be sufficient to permit Medicare, through its contractors, to review the appropriateness of Medicare payments made to the health care provider.
- Medicare pays claims if the items or services are accurately described, medically reasonable, medically necessary for the treatment or diagnosis of the patient's illness or injury, documented, and actually provided as represented to Medicare.
- Medicare does not pay for items or services that are not medically necessary.
- Medicare uses entities known as "MACs", Medicare Administrative Contractors, to process and pay Medicare claims.
- Medicare publishes guidance regarding what services it does and does not cover in a variety of publications, including National Coverage Determinations ("NCDs"), Local Coverage Determinations ("LCDs"), CMS program manuals.

- Medicare, through CMS and its contractors, will not pay claims for services (under Parts B and D) if it is determined the service was not rendered in accordance with program rules.
- Medicare beneficiaries typically have the choice as to which provider will provide services or items prescribed to them. Medicare generally prohibits a provider from directing an order or prescription to a particular company not of the patient's choosing.
- Rules and regulations also govern the alteration or falsification of medical records. Contractors who conduct audits and review look for alterations or falsifications in records when reviewing for fraud and abuse.
- The same coverage rules apply to a provider causing another enrolled provider to submit false claims to Medicare.
- Medicare cannot review every claim submitted because it would be physically impossible, for example there are over 1.2 billion claims submitted every year to Medicare.
- Payment of a claim by Medicare does not mean the claim is valid.
- Mr. Quindoza will provide examples of scenarios, under which controlled substances ordered by a provider (1) would not be considered reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of malformed body member or (2) would otherwise be ineligible for reimbursement. For example, controlled substances generally would not be considered reasonable and necessary if ordered by a provider who wrote the prescription outside the scope of their medical license not for legitimate medical purposes, or in other words, outside the usual course of professional practice not for legitimate medical purposes.

- Mr. Quindoza will apply his knowledge of Medicare rules and regulations regarding claims and reimbursement applied to the facts of this case.
- Mr. Quindoza will serve as a custodian of records for Medicare claims data and enrollment. Thus, the government intends to admit through this witness Medicare application(s) and Medicare claims data. Mr. Quindoza will authenticate and summarize Medicare claims data and admit enrollment documentation.
- Mr. Quindoza will provide testimony regarding summary exhibits that explain billing data and billing patterns in this case, including quantifying and summarizing the amounts billed and paid for items and services ordered by the Defendant, including for particular beneficiaries named in the Superseding Indictment.
- Mr. Quindoza will provide testimony regarding summary exhibits that explain billing data and billing patterns of the Defendant related to other services provided and items ordered as referring or rendering physician that were billed to Medicare, including instances and patterns of the Defendant submitting claims to Part B for services rendered to Medicare beneficiaries.

II. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

Mr. Quindoza is employed by SafeGuard Services LLC, a Unified Program Integrity Contractor that the CMS contracts with to identify and investigate suspected fraudulent activity and to protect the health care benefits for Medicare beneficiaries and Medicaid recipients in various states. Mr. Quindoza is responsible for outreach activities related to Medicare fraud and abuse, support and education to federal law enforcement agencies, training and development of staff, and

coordinating and sharing information with CMS, other Medicare contractors, and law enforcement agencies. Mr. Quindoza also personally worked in the processing and payment of Medicare claims submitted by a wide variety of providers. Mr. Quindoza's CV sets out his qualifications in greater detail.

Publications: Mr. Quindoza has not authored any publications in the previous ten years. He has, however, spoken at conferences and used visual aids (e.g., Microsoft PowerPoint slides) during such conferences.

III. List of Cases

Defense counsel will be provided via letter "a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition." Fed. R. Crim. P. 16(a)(1)(G)(iii). Please note that this list reflects Mr. Quindoza's best efforts to account for his expert testimony over the previous 4 years. Mr. Quindoza has been informed that if he learns of additional testimony that should be disclosed under this rule to notify the government.

Defense counsel will also be provided with a current curriculum vitae ("C.V.") for Mr. Quindoza. Mr. Quindoza developed summary charts under Rule 1006. These charts have been provided to defense counsel. If Mr. Quindoza is unavailable for trial, the Government reserves the right to call another employee or contractor of Medicare with similar qualifications and experience. That individual would render similar opinions and testify concerning the topics disclosed above.

Mr. Quindoza has reviewed and approved this disclosure as demonstrated by his attestation below.

I have reviewed and I approve this disclosure.

Date: 2/5/2023

Stephen Quindoza
Fraud Investigations Team Lead
SafeGuard Services LLC

NOTICE OF POTENTIAL EXPERT WITNESSES

Medicare Witnesses – Johanna Sullivan

I. Statement of Opinions, Bases, and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C), and the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii).

The Government intends to call Johanna Sullivan to explain how Medicare Part D works, Medicare's coverage for prescription drugs, how drug plans operate, about pharmacy practices, about Defendant's prescribing patterns, and about her report authored in this case and incorporated by reference.

Bases for Testimony:

Dr. Sullivan's proposed testimony is based upon her knowledge, skill, experience, training, and education in multiple positions relating to the practice of pharmacy and prescription claims analysis. Ms. Sullivan's opinions will also be based on her review and analysis of documents and claims data, which have been provided or made available as discovery to Defendant in this case and on rules, regulations, and reference materials cited in her expert report. Dr. Sullivan has knowledge, skill, experience, training, and education beyond the ordinary person regarding the practice of pharmacy, the practice of obtaining prescriptions from prescribers, prescription billing within the pharmacy industry, and the analysis of claims data as well as the meaning of trends and patterns within analyzed claims data. Dr. Sullivan's testimony will assist the jury in determining facts at issue in this case. In particular, during its case in chief, the United States expects to offer the testimony of Dr. Sullivan, based upon her special skill, training, and experience regarding the following issues:

Opinions and Summary of Anticipated Testimony: Dr. Sullivan wrote a report in this case that has been disclosed to Defendant. That report is incorporated into this disclosure and Dr. Sullivan will testify as to the content, facts, and opinions expressed in that report, as well as to the reference materials and data that are cited in that report. Dr. Sullivan will testify about summary charts and will testify to observations and opinions that are apparent in those charts. The government anticipates that Dr. Sullivan's testimony may also cover the following topics, including her background as included in her curriculum vitae ("CV"):

Information about the Medicare Program generally, including:

- The United States anticipates that Dr. Sullivan will provide overarching and background testimony concerning the Medicare Part D program.
- A beneficiary must enroll in a Medicare drug plan to receive Medicare Part D benefits. Medicare drug plans were operated by private health insurance companies approved by Medicare. Those companies were often referred to as Medicare drug plan "sponsors." A beneficiary in a Medicare drug plan could fill a prescription at a pharmacy and use their plan to pay for some or all of the prescription.
- A pharmacy could participate in Medicare Part D by entering a retail network agreement with one or more Pharmacy Benefit Managers ("PBMs"). A PBM acted on behalf of one or more Medicare drug plans. Through a plan's PBM, a pharmacy could join the plan's network. When a Medicare Part D beneficiary presented a prescription to a pharmacy, the pharmacy submitted a claim either directly to the Medicare drug plan sponsor or to a PBM that represented the beneficiary's Medicare drug plan. The Medicare drug plan sponsor or PBM determined whether the pharmacy was entitled to payment for each claim and periodically paid the pharmacy for outstanding claims.

The Medicare drug plan sponsor reimbursed the PBM for its payments to the pharmacy.

- Medicare, through CMS, compensated the Medicare drug plan sponsors. Medicare paid the sponsors a monthly fee for each Medicare beneficiary of the sponsors' plans. Such payments were called capitation fees. The capitation fee was adjusted periodically based on various factors, including the beneficiary's medical conditions. In addition, in some cases where a sponsor's expenses for a beneficiary's prescription drugs exceeded that beneficiary's capitation fee, Medicare reimbursed the sponsor for a portion of those additional expenses.
- Medicare Part D only reimburses for claims that are not pursuant to legitimate medical purposes and will not reimburse for claims do not comply with applicable federal and state laws.
- She will explain Medicare's reimbursement policies regarding dispensing medication and other pharmacy services.
- The United States further anticipates that Dr. Sullivan will provide more focused testimony about the Medicare prescription drug coverage, Medicare funding, claims processing, and payment. Dr. Sullivan will also discuss and explain how the Medicare billing system would and did process, adjudicate, and pay various claims, including claims and claims' data summaries for prescriptions written by Defendant, and the Medicare program's rules and regulations related thereto. Dr. Sullivan may discuss, authenticate, and introduce the following types of documents:
    - Medicare rules, regulations, and guidance;
    - Documents submitted to Medicare or a contractor related to a prescription written by Defendant;

- Claims submission and payment procedures for Medicare; and
- Prescription Drug Event ("PDE") records related to prescriptions written by Defendant.

- The Government anticipates Dr. Sullivan will testify concerning the application of Medicare's rules and regulations to prescriptions written by Defendant. This testimony would include:
  - Answer hypotheticals whether Medicare would, in various scenarios, knowingly pay for certain types of prescriptions;
  - that Medicare would not pay for a prescription not prescribed for a legitimate medical purpose or not in the usual course of professional practice.
  - will testify regarding summary exhibits explaining prescribing data and prescribing patterns in this case. Among other prescribing patterns, she may testify to the following and might use summary exhibits to explain these trends.
- Dr. Sullivan may testify about her analysis of PDE records, prescriptions, and data associated with Defendant and local pharmacies, including:
  - Patterns from the prescription data, including the percentage and volume of different prescriptions, long acting versus short acting opioid prescriptions, numbers by diagnosis code, frequency of certain diagnosis codes
  - Payment patterns
  - Volume of Defendant's prescriptions at pharmacies
  - Percentages of Defendant's patients on opioids, or opioids and other controlled substance combinations

- Convey specific claims information for the claims charged as substantive counts in the Superseding Indictment, such as the medication, the claim number, date of service, billing date, amount billed, prescription drug event codes, and national drug codes reflected in the billing data.
- Prescriptions for patients listed in the Superseding Indictment.
- Prescriptions filled for other patients of Defendant.
- Peer comparison of Defendant to all rural Tennessee prescribers who also participate in Medicare, demonstrating Defendant is in the top percentile among those physicians for prescribing controlled substances.

- Information about pharmacies, including:
  - The practice of pharmacy.
  - The operations of community and retail pharmacies, including drug purchasing practices.
  - Generic product identifiers, national drug codes, prescription billing and claims adjudication, and the ordinary and customary use of pharmacy billing software.
  - The purpose and role of medication in treating patients and the prescribing physician's role in selecting medication. The significance of drug interactions and contra-indications.
  - Indicators that a pharmacy's claims data reveal a pattern of billing or dispensing inappropriate prescriptions, including those written by Defendant.
  - Indicators that a CSMD/PDMP data reveal a pattern of dispensing inappropriate prescriptions, including those written by Defendant.

II. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

In 1995, Dr. Johanna Sullivan earned a Doctor of Pharmacy from the University of Florida, College of Pharmacy, where she graduated with High Honors. In 1996, she completed her Specialty Residency in Drug Information Practice at the University of Texas Health Science Center at San Antonio and the University of Texas at Austin College of Pharmacy. Dr. Sullivan is the Director of Clinical Operations of the Investigations Medicare Drug Integrity Contractor (IMEDIC), where she is responsible for coordinating pharmacist review for internal investigations and external law enforcement requests, among other responsibilities. From 2014 through 2018, Dr. Sullivan was the Lead Pharmacist for the National Benefit Integrity Medicare Drug Integrity Contractor (NBIMEDIC), where she also coordinated pharmacist review for internal investigations and law enforcement requests. Dr. Sullivan is a licensed pharmacist and a licensed consultant pharmacist in the State of Florida. A copy of Dr. Sullivan's curriculum vitae outlining her relevant background and experience has been provided to Defendant and is incorporated by reference.

Publications: Ms. Sullivan has written numerous publications that are listed on her incorporated CV.

III. List of Cases

Defense counsel will be provided via letter "a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition." Fed. R. Crim. P. 16(a)(1)(G)(iii). Please note that this list reflects Ms. Sullivan's best efforts to account for her expert testimony over the previous 4 years. She has been informed that if she learns of additional testimony that should be disclosed under this rule to notify the government.

The United States will seek to admit summary charts under Rule 1006 through Dr. Sullivan. These charts have been provided to defense counsel.

Ms. Sullivan has reviewed and approved this disclosure as demonstrated by her attestation below.

I have reviewed and I approve this disclosure.

Date: 2/6/2023

Johanna Sullivan PharmD
Director of Clinical Operations, MEDIC

NOTICE OF POTENTIAL EXPERT WITNESSES

TennCare Program – Aaron Butler, Director of Policy

I. Statement of Opinions, Bases and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C), and the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii).

The Government intends to call TennCare Director of Policy Aaron Butler, to testify regarding the TennCare program, managed care organizations, pharmacy benefit managers, the rules and regulations of the program, and Defendant's enrollment and contracts. The United States anticipates that Mr. Butler will provide overarching and background testimony concerning TennCare (Tennessee's Medicaid program). He will explain TennCare's coverage for physician services and prescription drugs, that all claims submitted for payment must be for reasonable and necessary items and services, and the representations that providers must make to enroll with TennCare. He will describe the rules in managed care contracts signed by the Defendant regarding the maintenance of medical records by providers, including alteration or falsification of records.

Bases for Testimony:

Mr. Butler's opinions will be based on his knowledge, training, skill, and experience working with the TennCare program including its rules and regulations, as well as his review and analysis of rules and regulations, which have been provided or made available as discovery to Defendant in this case. The witness did not write a report.

Opinions and Summary of Anticipated Testimony: The government anticipates Mr. Butler's testimony may cover the following topics:

Information about Medicaid and the TennCare program generally, including:

- He will testify that the TennCare program is Tennessee's state Medicaid program and that Medicaid is a federal health care program and a health care benefit program that is a partnership between the state and the federal government.
- His testimony may include that Centers for Medicare and Medicaid services oversees the program and that is part of the U.S. Department of Health and Human Services, a federal executive branch agency.
- The rules for TennCare Managed Care Organizations, including how Managed Care works in Tennessee and with the TennCare program.
- He will testify about how TennCare is administered and that indigent people and children, among others, are eligible to receive TennCare benefits.
- He will explain the services covered by TennCare, including physician services and pharmacy services.
- He may testify about what TennCare pays for and what is deemed medically necessary, how they pay claims, and requirements to participate.
- He may testify about how a physician enrolls with TennCare and then with a managed care organization, including what is required in order to bill claims for services provided to a beneficiary. For example, a primary care physician must be contracted with the managed care organization. He will testify that Defendant is a TennCare provider and will seek to introduce his application and discuss the contents of the application.
- Patients enroll with a managed care organization and see the physicians who are contracted with that managed care organization. The physician needs to be the

approved primary care physician for the patient in order to be reimbursed for services provided.

- He may testify about the managed care contracts and terms, the defendant's enrollment in TennCare, and that TennCare, through the managed care plans, does not pay for medically unnecessary services, and other rules of the program.
- He may explain the three managed care companies in TennCare and their contracts with providers, including Defendant's contracts. The contracts contain certification statements to comply with the rules and regulations of TennCare, including to act within the scope of the physician's license, order items or services that are reasonable and necessary, and also rules about maintaining medical records. He will explain that the contracts contain requirements to maintain medical records in their original form until the conclusion of audits, investigations, or prosecutions.
- The United States further his anticipates that Mr. Butler will provide testimony about Medicaid prescription drug coverage and Medicaid funding. The United States anticipates Mr. Butler testifying about how prescriptions are paid by TennCare through its pharmacy benefit manager. At the time of the charged conduct that entity was Magellan. He will testify about Magellan's contract with TennCare during the relevant indictment timeframe. The witness will explain how Magellan worked, what a pharmacy benefit manager means, and provide testimony about the prescription drug coverage, funding, claims processing, and payment through Magellan. Magellan had to follow TennCare's payment rules in reimbursing prescriptions.
- Providers have to comply with federal laws or payment by TennCare is not authorized. That includes complying with writing prescriptions for controlled substances in the

usual course of professional practice for legitimate medical purposes and acting within the scope of the physician's medical license.

- Mr. Butler will explain the nature of a claim and how it is submitted to TennCare, including what information is required to be on the claim. He will explain that even if a claim is submitted to a managed care organization or to a pharmacy benefit manager, it is ultimately TennCare who pays for it.
- TennCare relies on the truthfulness of providers and is a trust-based system.
- He may discuss or seek to introduce:
    - TennCare rules, regulations, and guidance; including the TennCare Administrative Rules;
    - Documents submitted to TennCare or a contractor related to a prescription written by Defendant;
    - TennCare Provider Participation Agreement and enrollment application;
    - TennCare's contracts with its managed care organizations;
    - Defendant's managed care contracts.
- The Government anticipates Mr. Butler will testify concerning the application of TennCare's rules and regulations to prescriptions. This testimony would include:
    - Hypotheticals on whether TennCare would, in various scenarios, knowingly pay for certain types of prescriptions;
    - Items and services must be medically necessary;
    - that TennCare would not pay for a prescription not prescribed for medically necessary reasons or not in compliance with state and federal laws,

including where not in the usual course of professional practice not for a legitimate medical purpose.

II. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

Aaron Butler's qualifications are described on his CV, previously provided to Defendant and incorporated by reference. Mr. Butler is the Director of Policy at TennCare and in that role he advises TennCare's leadership on their work with the federal government; particularly as it relates the TennCare 1115 demonstration, Tennessee's Medicaid State Plan, and Tennessee's CHIP State Plan. He serves as TennCare's primary point of contact with the Centers for Medicare & Medicaid Services (CMS) on issues related to the TennCare 1115 demonstration and the Medicaid and CHIP State Plans. He monitors the issuance of federal regulations, guidance, and policies related to Medicaid and CHIP, as well as monitors federal legislative developments with potential impacts on Medicaid and CHIP. Mr. Butler also coordinates the promulgation of state administrative rules for Tennessee's Medicaid and CHIP programs.

Publications: Mr. Butler has not authored any publications.

III. List of Cases

Below please find "a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition." Fed. R. Crim. P. 16(a)(1)(G)(iii). Mr. Butler previously testified as a 30(b)(6) witness in a deposition in the *case Strauser, et al. v. LaFrance Holdings, Inc., et al.*, Civ No. 4:18-cv-00673 (N.D. Ok.).

Mr. Butler has been informed that if he learns of testimony that should be disclosed under this rule to notify the government.

Mr. Butler has reviewed and approved this disclosure as demonstrated by his attestation below.

I have reviewed and I approve this disclosure.

Date: 2/6/2023

Aaron Butler, TennCare Director of Policy

NOTICE OF POTENTIAL EXPERT WITNESSES

Medical Coding and Health Information Management – Kristen Folding

Statement of Opinions, Bases and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C), and the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii).

The Government intends to call Kristen Folding, the Chief Executive Officer of Amenity Consulting, LLC. She will describe the various rules, regulations, practices, and contract provisions governing the maintenance and timeliness in medical record documentation and help the jury understand that alterations to medical records years after a patient visit are highly unusual and improper.

Bases for Testimony:

Ms. Folding's opinions will be based on her knowledge, training, skill, and experiences in the Health Information Management and coding field. She has served as a testifying subject matter expert witness in numerous cases, including trials in federal court, and has conducted many medical record reviews, medical coding and billing analysis, data analysis and fraud and abuse reviews. She is familiar with the rules and regulations of various federal health care programs and provider manuals and industry standards and will testify on the basis of those materials. She may also review medical records in this case, audit logs, and reports, and testify as to her opinions and observations.

Opinions and Summary of Anticipated Testimony: The government anticipates Ms. Folding's testimony may cover the following topics:

Information about Health Information Management generally, and specifically:

- She may testify about the medical industry standards on medical record documentation and the requirement that entries into medical records be timely. Complete and accurate and timely documentation is an important component of patient care in addition to providing a basis for payment at the time the services were rendered.
- She may testify that the Centers for Medicare and Medicaid Services (CMS) lays out specific guidelines of what is required in a medical record that supports claims submitted to Medicare and Medicaid. The Manuals also have rules on making addendums to medical records and what those rules are. The United States anticipates that she will testify that these manuals are publicly available to enrolled providers and are well known in the health care industry. She may testify that those rules were not followed by the Defendant when he made alterations to medical records.
- She may testify about evaluation and management coding documentation management guidelines and that entries into medical records must be complete and timely to support billed services.
- She may testify about state and federal regulations covering how long medical providers must maintain medical records for patients.
- She may testify regarding TennCare rules that are similar to Medicare rules in documentation practices and that entries be timely. She may testify that provisions within TennCare managed care contracts require providers maintain medical records in their original form until the conclusion of audits, investigations, or prosecutions.
- She may testify about Medicare audits of medical records and what auditors look for in the records, including alterations, late entries, and falsifications.

- She may review specific alterations made by the Defendant to medical records in this case and opine that they were not proper addendums or proper edits to the records and were untimely and not in compliance with the rules and regulations governing medical records. She may testify that it is highly unusual and contrary to industry practice to make alterations to medical records years after the services were provided, including when the records at issue are under any kind of audit or evaluation.

I. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

Kristen Folding's qualifications are described in her CV, provided to the Defendant and incorporated by reference. Ms. Folding has thirty (30) years of experience in the Health Information Management and coding field. She has provided and currently provides Subject Matter Expert services and assistance with fraud detection and data analysis to Department of Justice/United States Attorney Offices, Qui tam attorneys, other Law Enforcement Agencies, Program Safeguard Contractors (PSCs), Zone Program Integrity Contractors (ZPIC), Medicaid Integrity Contractors (MIC), Commercial, Medicare & Medicaid Managed Care Health Plans and other CMS/State Public Aid Contractors in pursuit of program integrity. She also provides Subject Matter Expert Witness and HIM consulting services on a limited basis to health care attorneys and facilities/providers. She currently is the owner and Chief Executive Officer of Amenity Consulting, LLC. She holds multiple certifications, including as an accredited healthcare fraud investigator, certified fraud examiner, and certified health data analyst, among others.

Publications: Ms. Folding has not authored any publications, but has presented on the topics described in this notice and as described in her C.V.

II. List of Cases

Below please find "a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition." Fed. R. Crim. P. 16(a)(1)(G)(iii). Ms. Folding has testified in several cases and a list will be provided contemporaneously with this disclosure to Defendant.

Ms. Folding has been informed that if she learns of testimony that should be disclosed under this rule to notify the government.

Ms. Folding has reviewed and approved this disclosure as demonstrated by her attestation below.

I have reviewed and I approve this disclosure.

Date: 02/06/23

Kristen Folding

Kristen Folding, RHIA, CFE, CHDA, AHFI

DISCLOSURE OF OTHER TESTIMONY AND EVIDENCE

The Government may call the following individuals as witnesses to (1) explain the extraction of digital evidence and to authenticate and admit such information, (2) describe and summarize financial transactions at issue in the case or quantify trends in the claims data identified and described by expert witnesses, (3) testify about their own medical treatment of Defendant's patients or observations of patients and discussions with Defendant about his prescribing.

Such testimony constitutes lay witness testimony pursuant to Federal Rules of Evidence 601, 602, 701, and does not constitute expert testimony under Rule 702. Nevertheless, the Government hereby notifies defense counsel of such evidence in case portions of the testimony are objected to as or are later deemed to be within the scope of Federal Rule of Evidence 702. All of these witnesses have been previously disclosed to Defendant. These witnesses may offer some or all of the following testimony.

DIGITAL EXAMINERS

Witnesses will be called who seized, copied, examined, and/or analyzed the content and data retrieved from digital devices seized from the medical clinic of the defendant. Lowell Floyd and Reginald Sparks are Digital Investigators with Department of Health & Human Services, Office of the Inspector General, Office of Investigations. Daniel Adami is a Senior Digital Forensics Analyst with CACI Digital Forensics Laboratory. A copy of each of their curriculum vitae has been previously provided to the Defendant. The witnesses will be asked to explain their training and background, the nature of the digital evidence, how it was seized and copied, the examination that they undertook of the digital evidence, the methods and/or software used to assist in the extraction and examination, and the evidence retrieved from the digital devices.

The United States intends to call Bharat Satyanarayan, Vice President of Technology and Quality Assurance from eClinicalWorks. Mr. Satyanarayan will be called to authenticate and admit records from eClinicalWorks. He will also testify about the extracted medical records from the electronic medical record system utilized by defendant, and the extractions at various times. Likewise, the witness will testify regarding internal messaging extracted from the eClinicalWorks system, used by defendant and his staff to communicate internally at the clinic. He will also testify and authenticate and admit audit trails and reports extracted from the eClinicalWorks that demonstrate when medical records were altered and identify the internet protocol address associated with the alterations.

Mr. Satyanarayan will be asked to explain his training and background, the nature of the electronic evidence, how it was extracted, the examination that they undertook, the methods and/or software used to assist, and the evidence extracted.

The United States will call Justin Reagan, or a similar custodian, from TwinLakes internet service provider to testify regarding the internet protocol address linked to the eClinicalWorks audit trail. This witness will describe how they extracted information to track the address to an account owned by the Defendant and at the Defendant's home address. This witness will authenticate and admit evidence associated with the account and internet protocol address.

As described above, these witnesses' anticipated testimony is more akin to that of a fact witness in that they will explain the evidence they located and how that evidence was located. Courts, including District Courts in the Middle District of Tennessee, have previously held that the extraction of information from a device, like a cellular telephone utilizing Cellebrite technology, does not qualify as expert testimony subject to Rule 702 of the Federal Rules of Evidence. However, the Government does anticipate eliciting testimony regarding multiple digital

devices and that may include metadata of some of the evidence recovered from the devices. Therefore, out of an abundance of caution, the United States discloses these witnesses.

FINANCIAL ANALYST

The Government will call Marylee Robinson, CPA, CFF, CFE, a Managing Director at Stout, Ross, Risisu, LLC, an advisory firm which has contracted with the United States to conduct financial analysis in this case. The witness will not be rendering expert opinion, nor medical opinion. Instead, Ms. Robinson may testify about patterns and trends, and explain summary exhibits, regarding otherwise voluminous information contained in the financial records and billing data. Summary exhibits have previously been disclosed to Defendant.

Ms. Robinson is a CPA, holds a CFE, a CFF, and a Masters of Business Administration with a concentration in accounting. Ms. Robinson's testimony will discuss bank record analysis and financial transactions involved in the case and summarize the flow of money in this case, including from various health care benefit programs to Defendant's bank accounts. This testimony may include a review of underlying financial records. Ms. Robinson may testify as to observations apparent from these summary charts and other exhibits.

CLAIMS DATA

The United States intends to call several witnesses to testify about the extraction of claims data in order to authenticate and admit the data. This includes multiple witnesses regarding the TennCare physician claims data and TennCare pharmacy claims data, and may include a witness from Magellan, TennCare's previous pharmacy benefit manager, who will testify as to how data is stored in a data warehouse and made available to the Tennessee Bureau of Investigation analysts. The United States will also call analysts who extracted the data. The data is voluminous. The analysts have created summary charts from TennCare claims data, the Defendant's patient data,

and the CSMD and may testify to observations apparent from the summary charts and other data. The United States may also call witnesses to testify about the extraction of voluminous Medicare data and metrics apparent from the data.

OTHER MEDICAL PROFESSIONALS

The United States intends to call witnesses in its case-in-chief who are medical professionals, including nurses, doctors, and pharmacists. Each will testify as a fact witness who observed and treated patients of defendant who were prescribed controlled substances. In the same vein, the Government may call one or more pharmacists who filled prescriptions written by the Defendant. Because such medical professionals will discuss their own factual observations, they are not expert witnesses, but lay witnesses. However, in an abundance of caution, and in the interests of full disclosure, the Government provides notice of the following witnesses, and the basic subjects of their testimony. The government considers these witnesses to be fact witnesses because they will testify about their observations based on their rational perceptions.

If the Government calls other providers, they may testify that they are aware of the patient, regarding their patients' diagnoses and health issues, and whether they are familiar with the Defendant or communicated with Defendant. Such testimony is factual under Rule 601 and 602. *See, e.g.*, *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1316 n.23 (11th Cir. 2014) ("A treating physician providing lay testimony can testify narrowly, limited to personal knowledge resulting from providing medical care, involving consultation, examination, or treatment of a potential plaintiff.") (citing *United States v. Henderson*, 409 F.3d 1293, 1300 (11th Cir. 2005)); *see also Davoll v. Webb*, 194 F.3d 1116, 1138 (10th Cir. 1999) ("A treating physician is not considered an expert witness if he or she testifies about observations based on personal knowledge, including the treatment of the party."); *Weese v. Schukman*, 98 F.3d 542, 550 (10th Cir. 1996)

(commenting that doctor's lay opinions "were based on his experience as a physician and were clearly helpful to an understanding of his decision making process in the situation."); *McFerrin v. Allstate Property & Cas. Co.*, 29 F. Supp. 3d 924, 933 (E.D. Ky. 2014).

Potential witnesses the United States may call that have medical knowledge include the following:

1. Michael Griffith: pharmacist;
2. Michael Choate: pharmacist;
3. Linda Conatser: pharmacist;
4. Carrie Cooper: pharmacy technician;
5. Todd Webb, MD: psychiatrist;
6. Carey Reed: Nurse Practitioner
7. Nurses who were former employees at GhearingMD, including Dawnda Frisa, Anne Kane, Whitney Frogge, Sara Hatcher, Victoria Smith, Charley Price, Vicki Hunley, Lori Russell, and Jessica Casey;
8. Medical Assistants who were former employees at GhearingMD, including Cheyenne Tipton;
9. Craig Shaffer, MD, who encountered defendant in the Marshall Islands prior to his move to Tennessee.

Respectfully submitted,

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Attorney for the United States
Acting Under Authority Conferred by
28 U.S.C. § 515

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CERTIFICATE OF THE SERVICE

I certify that a copy of the foregoing United States Revised Rule 16 Disclosure of Anticipated Expert Witnesses and Additional Evidence was served electronically, via ECF, this 7th day of February, 2023, upon counsel of record for the Defendant listed above.

s/Sarah K Bogni
SARAH K. BOGNI
Assistant U.S. Attorney